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(54) Implantable occluder device

(57) An occluder device (1) for a body duct comprises first and second expansion assemblies (2, 3) connected to each other and provided with attachment means (6) for connection to a wire and catheter positioning system, each assembly (2, 3) comprising a web of material (4) and at least three resilient arms (5) projecting, when undeformed, radially from the device and carrying the web (4), the arms being resiliently biased apart to open up and resiliently deformable to close down the associated web in an umbrella-like manner. The assemblies (2, 3) are joined at their central portions and arranged oppositely to each other. Each arm (5) is bent through an angle such that, when the webs (4) are opened up, the distal ends of the arms (5) of each web point generally towards the other web and the two webs are biased into contact with one another at their peripheries.

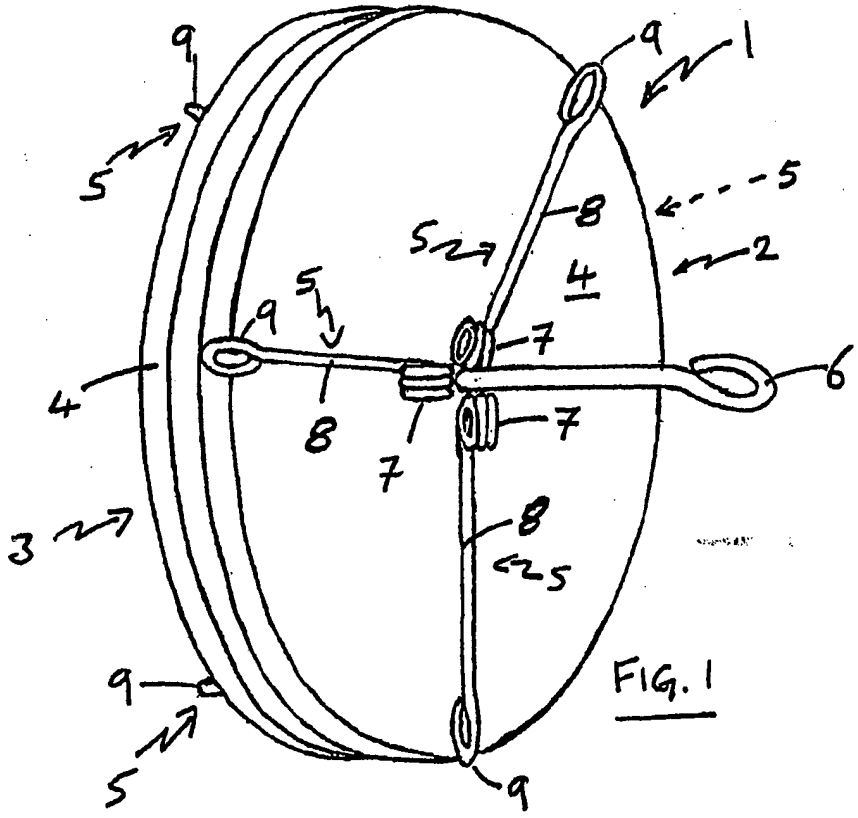

FIG. 1

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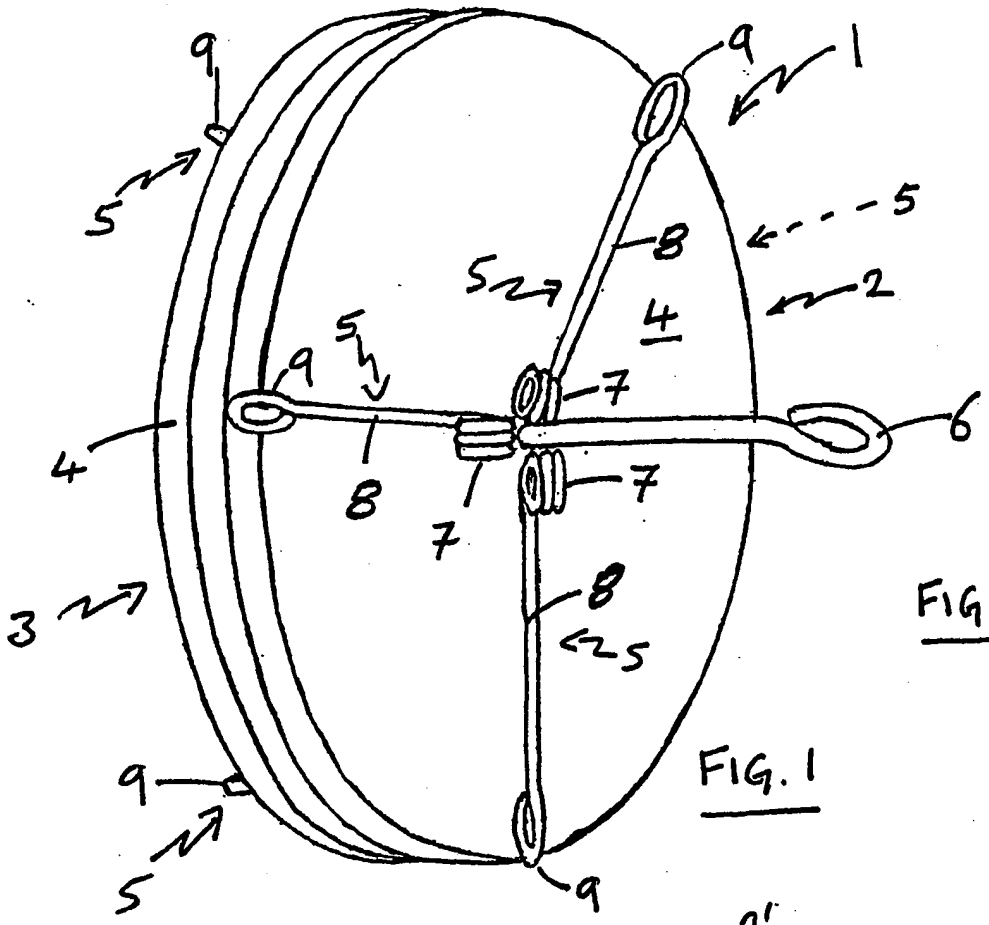

FIG. 1

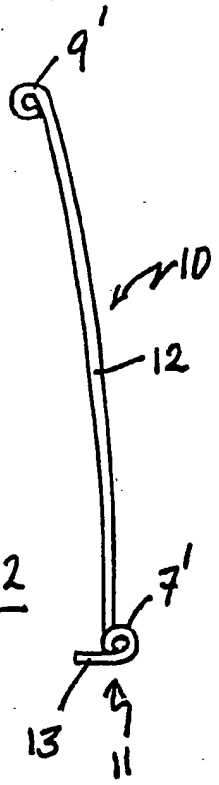

FIG. 2

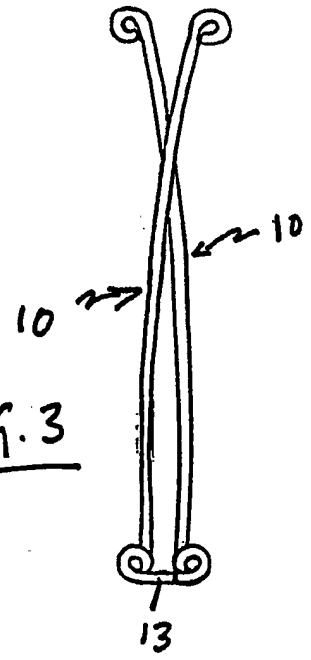

FIG. 3

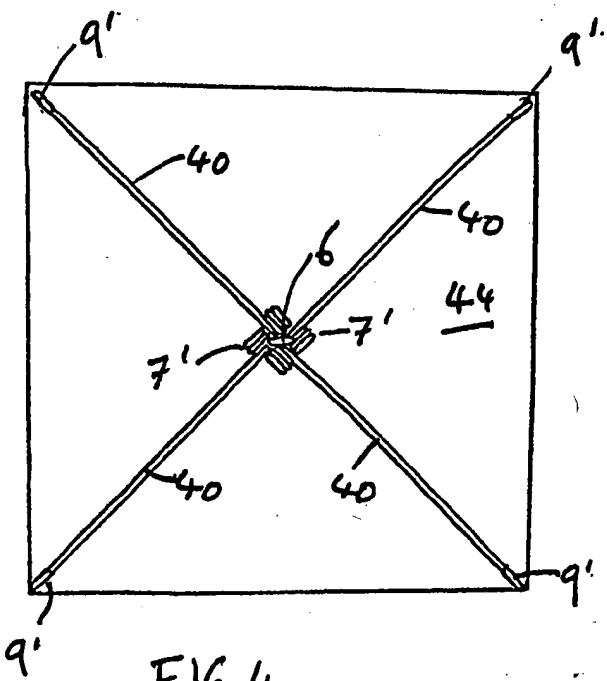

FIG. 4

Implantable occluder devices for medical use

This invention relates to implantable occluder devices for medical use.

A known implantable occluder device for medical use is the USCI Rashkind Occluder Implant (USCI is a Trademark and Rashkind is a Registered Trademark of William J. Rashkind, M.D., licensed to C. R. Bard, Inc.) sometimes called the "Rashkind ductal umbrella". The Rashkind Occluder Implant resembles two miniature umbrellas joined in a straight line, top end to top end, each of the two "umbrellas" comprising a respective disk of foam plastics material (corresponding to the fabric of an umbrella) carried on resilient wire arms (corresponding to the spokes of an umbrella).

The Rashkind Occluder Implant is used to occlude a blood vessel, for example, an arterial duct which is an abnormal blood vessel connecting the two major arteries in the body. The implant is deployed, with the "umbrellas" closed and sheathed, using a wire and catheter positioning system passed through a vein of the patient. When the implant is correctly positioned the sheath is removed by the doctor operating the positioning system and the resilient wire arms bias the umbrellas open against the walls of duct to create an occlusion.

The Rashkind Occluder Implant is made in a 12mm size for ducts of up to 3mm narrowest diameter and in a 17mm

size for ducts of 4mm to 9mm narrowest diameter. When the implant is in position in the duct with the "umbrellas" opened up, its shape resembles that of an hour glass and the resilient bias of the spring arms holds it firmly in position.

Unfortunately, although the Rashkind Occluder Implant is highly successful for the occlusion of ducts, it is not suited to the occlusion of orifices in a thin wall of tissue such as atrial septal defects (either naturally occurring or those left after surgery) in the heart. That is because the Rashkind Occluder Implant is unable to grip a thin object placed between the "umbrellas". For that purpose, a so-called "clamshell" implant was developed by James Lock, M.D.

The Lock clamshell implant is generally similar to the Rashkind Occluder Implant except that the spokes of the "umbrellas" are given a more complex form. In the Lock clamshell, each wire arm of the Rashkind Occluder, instead of running straight from its base portion, is wound part-way along its length into a tiny torsion spring. These torsions springs serve to bias the periphery of one "umbrella" back against the other "umbrella" so as to grip the wall of tissue with the orifice to be occluded.

The torsion springs enable the Lock clamshell implant to gain a firm purchase on the wall of tissue and that, at first sight, is a satisfactory solution to the

problem of occluding an orifice in a thin wall of tissue. In practice, however, the solution has been found to be unsatisfactory because the wire arms exhibit a tendency to fracture at the torsion springs.

The Rashkind Occluder Implant has itself a tiny torsion spring at the base of each wire arm and in view of the practical experiences with the Lock clamshell device, it would be undesirable to increase the stress on those springs in an attempt to make a Rashkind Occluder Implant capable of gripping a wall of thin tissue more firmly.

It also has to be borne in mind that the implant has to be deployed via a vein of the patient and there are therefore practical limitations on the size of the implant has when it is closed up.

It is an object of the invention to provide an implantable occluder device suited to positioning by a transcatheter technique and suited to occluding an orifice in a thin wall of tissue but without the torsion springs part-way along the length of the arms that are prone to breakage in the known Lock clamshell device.

The present invention provides an implantable occluder device for medical use comprising first and second expansion assemblies connected to each other and provided with attachment means for connection to a wire and catheter positioning system, each expansion assembly comprising a respective web of material and at least

three resilient arms projecting, when undeformed, substantially radially from the device and carrying the web of material, the arms being resiliently biased apart to open up, and being resiliently deformable to close down, the associated web of material in a manner similar to that in which the spokes of an umbrella open up and close down the fabric of the umbrella, the first and second expansion assemblies being joined at their central portions and arranged oppositely with the distal ends of the arms of the first expansion assembly being remote from the distal ends of the arms of the second expansion assembly when the webs are closed down, characterized in that each arm is bent, by means of an open curve extending uninterruptedly from a base portion to a distal portion of the arm, through an angle such that, when the webs are opened up, the distal ends of the arms of each web point generally towards the other web and the two webs are biased into contact with one another at their peripheries.

Such a device is able to make use of the inherent resilience of the arms to grip a thin wall of tissue located between the webs and can be used, for example, to occlude naturally occurring and surgically created atrial septal defects as well as ventricular septal defects. Wher as the arms of a device according to the invention have an open curved construction, in th Lock clamshell device each arm was bent into a closed curve several

times over to form a torsion spring part way between the base portion and the distal portion of the arm.

Moreover, although it might be thought that in a device in accordance with the invention, the arms could not be closed down satisfactorily for deployment, or that when closed down would become permanently deformed or break, the arms can, in fact, be resiliently deformed, in the closed up state, towards a straight configuration without breaking and still regain their shape satisfactorily on opening up again.

Preferably, the said angle is greater than 10 degrees and less than 40 degrees, more preferably the said angle is greater than 10 degrees and less than 30 degrees, and yet more preferably the said angle is greater than 10 degrees and less than 20 degrees. The angle may be approximately 15 degrees. Such shallow curves are particularly suitable.

Preferably, the base portion of each arm includes a respective torsion spring formed out of the material of the arm and arranged to bias the associated arm to open up the web. That provides a very simple way of applying additional spring bias to open up the web.

Preferably, the arms of each expansion assembly are substantially equally spaced and the arms of one expansion assembly are offset with respect to the arms of the other expansion assembly and bisect approximately th angles between the arms of the other expansion ass mbly.

With such an arrangement, the webs may be arranged to open up to an extent that, in the absence of an external object, the distal ends of the arms of one expansion assembly cross over the arms of the other expansion assembly. Such an arrangement provides a particularly good grip on a thin wall of tissue.

Each arm may follow a smooth shallow curve in bending through the said angle. Such a curve is particularly suitable.

The maximum departure of each arm from a straight line may be less than three millimetres and preferably is less than two millimetres. Good results can be achieved with such a construction in a device of 12 or 17 mm diameter but larger constructions are also possible.

Preferably, the arms are made of stainless steel. Such a material provides the required resilience, is acceptable to the human body and resistant to corrosion.

Preferaby, the webs are of foam plastics material. Such material is easily opened up under the bias of the arms and provides a good site for the build up of a clot of blood and for tissue overgrowth.

Each expansion assembly may have three arms. The use of three arms provides both simplicity of construction and satisfactory support for the webs.

Instead, ach expansion assembly may have four arms. Such an arrangement is only slightly less simpl but provides better support for the webs. If desired, each

expansion assembly may have more than four arms.

The webs may be circular or they may be square. Such shapes are simple and of the most general usefulness although other shapes are also possible.

The invention also provides an occlusion system comprising an implantable occluder device in accordance with the invention and a wire and catheter positioning system for deploying the device.

Implantable occluder devices constructed in accordance with the invention will now be described, by way of example only, with reference to the accompanying drawing, in which:

Figure 1 is a perspective view of the known Rashkind Occluder Implant;

Figure 2 is a side view, to a larger scale, of an arm of an implantable occluder device in accordance with the invention;

Figure 3 is a diagrammatic illustration showing how the distal ends of the arms of the occluder device of Figure 2 tend to overlap, and

Figure 4 is a front view, to a smaller scale, of a square implantable occluder device in accordance with the invention.

Referring to the accompanying drawings, Figure 1 shows the known Rashkind Occluder Implant 1. The implant consists of two expansion assemblies 2, 3 somewhat like two miniature umbrellas joined in a straight lin , top

end to top end.

Each expansion assembly 2,3 consists of a circular disk 4 of PTFE foam carried on three stainless steel wire arms 5. An attachment eye 6, formed integrally on a length of stainless steel wire, projects from one face of the expansion assembly 2. Each wire arm 5 consists of a base portion including an integral torsion spring 7, a straight body portion 8, and an integral eye 9 at the distal end of the wire arm. The base portions of all the wire arms 5 and the base of the wire of the attachment eye 6 are hard soldered together in the centre of the implant beteen the two disks 4 and the eyes 6 and 9 are hard soldered closed. Each disk 4 is secured to the associated arms 5 both by means of an adhesive and by sewing with a thread of plastics material (not shown).

The three arms 5 of each disk 4 are spaced at approximately 120 degree intervals and the arms of one disk are angularly offset with respect to the arms of the other disk so as to bisect approximately the angle between the arms of the other disk.

The arms 5 correspond to the spokes of an umbrella and bias the disks open to the position shown in Figure 1. By means of the attachment eye 6, the implant 1 can be attached to a knuckle on the end of a wire passing through a catheter. By means of lin s attach d to the eyes 9 of the arms 5 of the disk 4 r mote from the attachment y 6 (that is, the disk 4 of the xpansion

assembly 3), the arms can be pulled against the bias of the torsion springs 7 to close down the expansion assembly 3 and draw it through a funnel shaped passage into a sheath, the expansion assembly 2 closing down as it too is pulled into the funnel shaped passage.

Once inside the sheath, the lines attached to the eyes 9 are detached and the implant is ready for deployment.

An implantable occluder device in accordance with the invention corresponds to the Rashkind Occluder Implant 1 just described except that the arms 5 are replaced by arms 10 in accordance with the invention. Referring to Figure 2, an arm 10 for an implant device in accordance with the invention comprises a length of stainless steel wire of the same gauge as that used in the known implant defining a base portion 11 with an integral torsion spring 7′, a body portion 12, and an eye 9′ constituting the distal portion of the arm. The torsion spring 7′ has a projecting end 13 to be hard soldered to the projecting ends of the other arms of the device.

On leaving the torsion spring 7′, the body portion 12 exits at an angle of approximately 90 degrees to the longitudinal axis of the device and bends gradually by means of a smooth, shallow open curve through an angle of approximately 15 degre s. The curve is preferably one which most readily permits the arm to be r siliently

deformed to a straight condition for deployment. A satisfactory curve can be achieved by permanently bending an intitially straight arm approximately 1 to 2 mm at its mid-point to produce a smooth curve along the body portion of the arm.

Figure 3 illustrates diagrammatically how the arms 10 of one expansion assembly in a device in accordance with the invention tend to overlap the arms of the other expansion assembly. The figure shows two arms as they would appear if seen side-by-side, instead of the true 60 degrees apart, and with no intervening material. Each arm tries to push its associated web into the other web with the result that in the absence of an intervening object each web is folded at three places into the other web. Such an arrangement gives a good grip on a thin wall of tissue placed between the webs.

A second implant device in accordance with the invention is shown in Figure 4 and has eight arms 40 of the same construction as the arms 10 just described. The round disks 4 of Figure 1 are here replaced by square disks 44 with the four arms for each disk arranged diagonally.

The occluder devices embodying the invention are deployed using the same wire and catheter positioning system and method as in the prior art.

C L A I M S:

1. An implantable occluder device for medical use comprising first and second expansion assemblies connected to each other and provided with attachment means for connection to a wire and catheter positioning system, each expansion assembly comprising a respective web of material and at least three resilient arms projecting, when undeformed, substantially radially from the device and carrying the web of material, the arms being resiliently biased apart to open up, and being resiliently deformable to close down, the associated web of material in a manner similar to that in which the spokes of an umbrella open up and close down the fabric of the umbrella, the first and second expansion assemblies being joined at their central portions and arranged oppositely with the distal ends of the arms of the first expansion assembly being remote from the distal ends of the arms of the second expansion assembly when the webs are closed down, characterized in that each arm is bent, by means of an open curve extending uninterruptedly from a base portion to a distal portion of the arm, through an angle such that, when the webs are opened up, the distal ends of the arms of each web point generally towards the other web and the two webs are biased into contact with one another at their peripheries.

2. An implantable occluder device as claimed in

claim 1, wherein the said angle is greater than 10 degrees and less than 40 degrees.

3. An implantable occluder device as claimed in claim 2, wherein the said angle is greater than 10 degrees and less than 30 degrees.

4. An implantable occluder device as claimed in claim 2, wherein the said angle is greater than 10 degrees and less than 20 degrees.

5. An implantable occluder device as claimed in claim 4, wherein the said angle is approximately 15 degrees.

6. An implantable occluder device as claimed in any preceding claim, wherein the base portion of each arm includes a respective torsion spring formed out of the material of the arm and arranged to bias the associated arm to open up the web.

7. An implantable occluder device as claimed in claim 6, wherein each arm leaves its associated torsion spring substantially at right angles to the longitudinal axis of the device.

8. An implantable occluder device as claimed in any preceding claim, wherein the arms of each expansion assembly are substantially equally spaced and the arms of one expansion assembly are offset with respect to the arms of the other expansion assembly and bisect approximately the angles between the arms of the other expansion assembly.

9. An implantable occluder device as claimed in claim 8, wherein the webs are arranged to open up to an extent that, in the absence of an external object, the distal ends of the arms of one expansion assembly cross over the arms of the other expansion assembly.

10. An implantable occluder device as claimed in any preceding claim, wherein each arm follows a smooth, shallow curve in turning through the said angle.

11. An implantable occluder device as claimed in any preceding claim, wherein the maximum departure of each arm from a straight line is less than three millimetres.

12. An implantable occluder device as claimed in claim 11, wherein the maximum departure of each arm from a straight line is less than two millimetres.

13. An implantable occluder device as claimed in any preceding claim, wherein the arms are made of stainless steel.

14. An implantable occluder device as claimed in any preceding claim wherein the webs are of foam plastics material.

15. An implantable occluder device as claimed in any preceding claim, wherein each expansion assembly has three arms.

16. An implantable occluder device as claimed in any one of claims 1 to 14, wherein each expansion assembly has four arms.

17. An implantable occluder device as claimed in any preceding claim wherein the webs are circular.

18. An implantable occluder device as claimed in any one of claims 1 to 16, wherein the webs are square.

19. An implantable occluder device substantially as herein described with reference to and as illustrated by Figure 2 of the accompanying drawing.

20. An implantable occluder device substantially as herein described with reference to and as illustrated by Figure 4 of the accompanying drawing.

21. A occlusion system comprising an implantable occlusion device as claimed in any preceding claim and a wire and catheter positioning system for deploying the device.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

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Relevant Technical fields

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(ii) Int Cl (Edition 5) A61B, A61M

Search Examiner

L V THOMAS

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASES: WPI, CLAIMS, MEDLINE

Date of Search

11 NOVEMBER 1992

Documents considered relevant following a search in respect of claims 1-21

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
A	GB 1509023 (ALTON OCHSNER) See lines 40-98 page 2	1
A	GB 1500470 (AMERICAN HOSP SUPPLY) See lines 63-83 page 1 and Figures 1 and 4	1
X	US 5108420 (MARKS) See line 50 column 1 - line 12 column 2 and lines 3-37 column 3 (note reference to spring steel in line 23	1, 10, 13, 15-17 21

Category	Identity of document and relevant passages	Relevant t claim(s)

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